

**§314.96 Amendments to an unapproved abbreviated application.**

(a) *Abbreviated new drug application.*

(1) An applicant may amend an abbreviated new drug application that is submitted under §314.94, but not yet approved, to revise existing information or provide additional information.

(2) Submission of an amendment containing significant data or information constitutes an agreement between FDA and the applicant to extend the review period only for the time necessary to review the significant data or information and for no more than 180 days.

(3) Submission of an amendment containing significant data or information to resolve deficiencies in the application as set forth in a not approvable letter issued under §314.120 constitutes an agreement between FDA and the applicant under section 505(j)(4)(A) of the act to extend the date by which the agency is required to reach a decision on the abbreviated new drug application only for the time necessary to review the significant data or information and for no more than 180 days.

(b) The applicant shall submit a field copy of each amendment to §314.94(a)(9). The applicant, other than a foreign applicant, shall include in its submission of each such amendment to FDA a statement certifying that a field copy of the amendment has been sent to the applicant's home FDA district office.

(c) *Abbreviated antibiotic application.* The applicant shall comply with the provisions of §314.60.

[57 FR 17983, Apr. 28, 1992, as amended at 58 FR 47352, Sept. 8, 1993]

**§314.97 Supplements and other changes to an approved abbreviated application.**

The applicant shall comply with the requirements of §§314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

**§314.98 Postmarketing reports.**

(a) Except as provided in paragraph (b) of this section, each applicant having an approved abbreviated antibiotic application under §314.94 or approved abbreviated new drug application under

§314.94 that is effective shall comply with the requirements of §314.80 regarding the reporting and record-keeping of adverse drug experiences.

(b) Each applicant shall submit one copy of each report required under §314.80 to the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Each applicant shall make the reports required under §314.81 and sections 505(k) and 507(g) of the act for each of its approved abbreviated applications.

**§314.99 Other responsibilities of an applicant of an abbreviated application.**

(a) An applicant shall comply with the requirements of §314.65 regarding withdrawal by the applicant of an unapproved abbreviated application and §314.72 regarding a change in ownership of an abbreviated application.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§314.92 through 314.99. The applicant shall comply with the requirements for a waiver under §314.90.

**Subpart D—FDA Action on Applications and Abbreviated Applications**

SOURCE: 50 FR 7493, Feb. 22, 1985, unless otherwise noted. Redesignated at 57 FR 17983, Apr. 28, 1992.

**§314.100 Timeframes for reviewing applications and abbreviated applications.**

(a) Within 180 days of receipt of an application for a new drug under section 505(b) of the act, or of an abbreviated application for a new drug under section 505(j) of the act, or of an application or abbreviated application for an antibiotic drug under section 507 of the act, FDA will review it and send the applicant either an approval letter under §314.105, or an approvable letter under §314.110, or a not approvable letter under §314.120. This 180-day period is called the "review clock."

(b) During the review period, an applicant may withdraw an application